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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/638,173	08/06/2003	Robert Kain	ILLINC.026C1	3813

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KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER

FORMAN, BETTY J

ART UNIT	PAPER NUMBER
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1634

NOTIFICATION DATE	DELIVERY MODE
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06/26/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
eOAPilot@kmob.com

Office Action Summary	Application No.	Applicant(s)	
	10/638,173	KAIN ET AL.	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 60,61,63,65-72,74,76-84,86,88-99 and 101-125 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 60,61,63,65-72,74,76-84,86,88-99 and 101-125 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/07, 12/07, 1/08</u> . | 6) <input type="checkbox"/> Other: _____ |

FINAL ACTION

Status of the Claims

1. This action is in response to papers filed 11 March 2008 in which claims 60, 65, 71, 76, 83, 88, 94, 101 were amended, claims 62, 64, 73, 75, 85, 87, 98, 100 were canceled and claims 118-125 were added. All of the amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 11 October 2007 under 35 U.S.C. 112, second paragraph are withdrawn in view of Applicant's remarks on pages 11-12 of the response. The previous rejections under 35 U.S.C. 102(e) and 35 U.S.C. 103(a) are withdrawn in view of the amendments.

Applicant's arguments have been thoroughly reviewed but are deemed moot in view of the amendments, withdrawn rejections and new grounds for rejection. New grounds for rejection, necessitated by the amendments, are discussed.

Claims 60-61, 63, 65-72, 74, 76-84, 86, 88—98, 99, 101-125 are under prosecution.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made

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to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 60-125 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walt et al (U.S. Patent No. 6,327,410, filed 11 September 1998) in view of Felder et al (U.S. Patent No. 6,323,066, filed 2 July 1998).

Regarding Claim 60, 65, 71, 76, 83, 88, 96, 101, Walt et al disclose an array and method of making the array comprising a substrate having a surface (Column 5, lines 32-60), a first assay location and second assay location on the surface (Column 5, line 61-Column 6, line 30), wherein the substrate has a first plurality of depressions in first and second assay locations and first and second microsphere populations having both genomic and non-genomic (cDNA) DNA (Column 10, lines 26-31) randomly placed in the assay locations wherein the assay locations spatially identifiable manually (Column 18, line 59-Column 18, line 5) and wherein the depressions have a single microsphere (Column 6, lines 16-21) and wherein the substrate is an optical fiber (Column 5, lines 57-60).

Walt et al teach the assay locations spatially identifiable manually but they do not specifically teach the assay locations are separated.

However, array locations separated by gaskets were well known in the art at the time the claimed invention was made as taught by Felder et al (Fig. 4-5).

Felder et al teach a substrate (Column 5, lines 1-13) having a plurality of assay locations (regions), each having a subpopulation of bioactive agents (e.g. genomic DNA, Column 6, lines 52-67) wherein the assay locations are separated by a gasket

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forming an array of wells-within-wells (e.g. wax or silicone barriers/well separator, Column 5, lines 19-59; Column 6, lines 38-51; Column 13, lines 1-22; and Fig. 5) whereby the assay locations are spatially discrete, identifiable and addressable within a fluidically controlled environment (Column 5, lines 19-59).

Walt clearly desires segregation of the subpopulations to provide spatial encoding of the microspheres and suggests manual techniques to do so (Column 18, line 59-Column 19, line 5). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the barrier elements of Felder et al to the substrate of Walt et al. One of ordinary skill in the art would have been motivated to do so based on the desired segregation of Walt et al and further for the expected benefit of providing for fluidically controlled multi-sample testing without cross contamination between adjacent regions as taught by Felder et al (Column 5, lines 19-59).

Regarding Claim 61, 72, 84, 97, Walt et al teach the array and method wherein “substantially” all the wells have a microsphere (Fig. 7).

Regarding Claim 63, 74, 86, 99, Walt et al teach the array wherein the microspheres are in optical channels for detection (Column 13, lines 8-44, Column 16, lines 21-53).

Regarding Claim 66, 77, 89, Walt et al teach the array wherein the bioactive agent is DNA (Column 10, lines 28-35).

Regarding Claim 67, 78, 90, 102, Walt et al teach the array wherein the support is planar glass (Column 5, lines 57-60) and Felder et al teach the similar array wherein the support is a glass slide (Column 5, line 2).

Regarding Claims 68, 79, 91, 103, Walt et al teach the array is within a hybridization chamber (Fig. 4) and Felder et al teach the similar array within a hybridization chamber (Column 9, lines 13-61).

Regarding Claims 69-70, 80-81, 92-93, 104-105, Walt et al teach the array wherein the substrate comprises a membrane i.e. over the beads (Column 6, lines 45-47) and Felder et al teach the similar array wherein the substrate comprises a membrane wherein the barrier material flow into and seal the pores to create the barrier between the assay regions and separate hybridization regions within the hybridization chamber (Column 5, lines 1-4).

Regarding Claim 106, Walt et al teach the depressions are wells (Column 6, lines 16-30). Felder et al teach the depressions are wells (Column 6, lines 38-51).

Regarding Claim 107-108, Walt et al teach the method further comprising preparation of the DNA by PCR (Column 23, lines 5-8).

Regarding Claim 109-111, Walt et al teach the method wherein the bioactive agent is DNA (Column 10, lines 28-35) and the method includes sequencing (Column 24, lines 51-52). While Walt et al teaches the array is used for sequencing, the sequencing practiced with the array produced by the method, does not further define the method of making the array. As such, the recited sequencing methods do not

further define the method of Claim 94 for making the array. Furthermore, Felder et al teaches the similar method determines the sequence (column 11, lines 23-48).

Regarding Claims 112-117, Walt et al teach the arrays and methods wherein each subpopulation is randomly distributed such that members of each subpopulation are in multiple sub-bundles (Column 18, line 48-Column 19, line 53).

Regarding Claims 119-125, Felder et al teach the method and array wherein the gasket is provided in a variety of shapes e.g. wax or silicone (Column 5, line 41). While the references do not specifically teach a tube shaped gasket, the courts have stated that claimed dimensions of a known device do not distinguish over the prior art device when the claimed device would not perform differently from the prior art device. *In Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984), the Federal Circuit held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device.

The courts have stated that absent evidence to the contrary, a particular configuration of a known device is a matter of choice which would have been obvious to one skilled in the art. *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966) (The court held that the configuration of the claimed disposable plastic nursing container was a matter of choice which a person of ordinary skill in the art would have found obvious

absent persuasive evidence that the particular configuration of the claimed container was significant.).

Therefore, the instantly claimed gasket shape would have been an obvious variation of the gaskets taught by Felder.

Conclusion

4. No claim is allowed.
5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BJ Forman
Primary Examiner
Art Unit 1634

/BJ Forman/
Primary Examiner, Art Unit 1634